IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

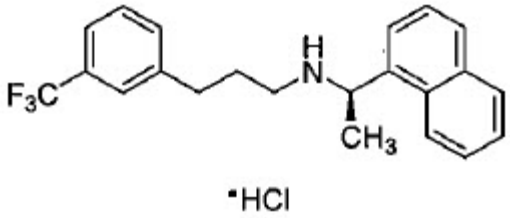
THE BRIGHAM AND WOMEN'S HOSPITAL, INC., NPS PHARMACEUTICALS, INC. and AMGEN INC., Plaintiffs, vs. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD. and BARR LABORATORIES, INC. Defendants.	C.A. No. 08-464-HB **JURY TRIAL DEMANDED**

DEFENDANT BARR'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND JURY DEMAND

Defendant Barr Laboratories, Inc. ("Barr") by and through its undersigned attorneys answers the Complaint of The Brigham and Women's Hospital, Inc., NPS Pharmaceuticals, Inc. and Amgen Inc. (collectively "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 6,211,244 ("the '244 patent"), United States Patent No. 6,313,146 ("the '146 patent"), United States Patent No. 6,011,068 ("the '068 patent") and United States Patent No. 6,031,003 ("the '003 patent") (collectively referred to as "the Patents") arising under United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. The Patents collectively claim, *inter alia*, cinacalcet hydrochloride as well as pharmaceutical compositions containing cinacalcet hydrochloride, and methods of treatment administering cinacalcet hydrochloride. The chemical structure for cinacalcet hydrochloride is:



ANSWER: On information and belief, Barr admits that Plaintiffs brought this patent litigation, but otherwise deny the allegations of paragraph 1.

2. This action relates to Teva Pharmaceuticals USA, Inc.'s and Barr Laboratories, Inc.'s filings of Abbreviated New Drug Applications ("ANDAs") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 335(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

ANSWER: Barr admits that it filed with the FDA an ANDA seeking approval to market a generic pharmaceutical product, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2 and therefore denies them.

PARTIES

3. The Brigham and Women's Hospital, Inc. ("BWH") is a hospital organized and existing under the laws of the State of Massachusetts. Its principal place of business is located at 75 Francis Street, Boston, Massachusetts, 02115.

ANSWER: On information and belief, Barr admits the allegations of paragraph 3.

4. NPS Pharmaceuticals, Inc. ("NPS") is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at 550 Hills Drive, 3rd Floor, Bedminster, New Jersey 07921-1537.

ANSWER: On information and belief, Barr admits the allegations of paragraph 4.

5. Amgen, Inc. ("Amgen") is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

ANSWER: On information and belief, Barr admits the allegations of paragraph 5.

6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454.

ANSWER: On information and belief, Barr admits the allegations of paragraph 6.

7. Upon information and belief, Defendant Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") is a corporation organized under the laws of Israel, having its principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

ANSWER: On information and belief, Barr admits the allegations of paragraph 7.

8. Upon information and belief, Defendant Teva USA is a wholly-owned subsidiary of Teva Ltd.

ANSWER: On information and belief, Barr admits the allegations of paragraph 8.

9. Teva USA and Teva Ltd. are hereinafter collectively referred to as "Teva."

ANSWER: This is a general statement regarding Plaintiffs' usage and requires no further response.

10. Upon information and belief, Defendant Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 255 Summit Avenue, Montvale, New Jersey 07645.

ANSWER: Barr admits the allegations of paragraph 10.

11. The New York Times has reported that Teva Ltd. will purchase Barr and that Teva Ltd. expects the deal will close in late 2008.

ANSWER: Barr admits the allegations of paragraph 11.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States and the Food and Drug laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Barr admits that this Court has subject matter jurisdiction for claims of patent infringement.

13. Upon information and belief, this Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief; Teva USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva USA's generic product.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 and therefore denies them.

14. Upon information and belief, this Court has personal jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), conducts business within this judicial district. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 and therefore denies them.

15. Upon information and belief, this court has personal jurisdiction over Barr. Upon information and belief, Barr is a corporation organized and existing under the laws of the State of Delaware.

ANSWER: Barr admits the allegations of paragraph 15.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ANSWER: Barr admits that venue is proper in this judicial district, but denies the remaining allegations of paragraph 16.

FIRST CLAIM FOR RELIEF

17. Plaintiffs incorporate and reallege paragraphs 1-16 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-16.

18. United States Patent No. 6,211,244, entitled "Calcium Receptor-Active Compounds," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 3, 2001. A copy of the '244 patent is attached hereto as Exhibit A.

ANSWER: Barr admits that the '244 patent states on its face an issue date of April 3, 2001 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 18.

19. The '244 patent is assigned to NPS and NPS is the owner of the '244 patent.

ANSWER: On information and belief, Barr admits that the '244 patent is assigned to NPS.

20. Amgen has been and is the exclusive licensee of the '244 patent in the United States under a "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '244 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20.

21. Amgen holds an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 21.

22. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 22.

23. The '244 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 23.

24. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 and therefore denies them.

25. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '244 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 and therefore denies them.

26. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 and therefore denies them.

27. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 and therefore denies them.

28. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '244 patent is invalid, not infringed and/or unenforceable.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 and therefore denies them.

29. Teva has infringed at least one claim of the '244 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the `244 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 and therefore denies them.

30. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '244 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 and therefore denies them.

31. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '244 patent under 35 U.S.C. § 271(e)(4).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 and therefore denies them.

SECOND CLAIM FOR RELIEF

32. Plaintiffs incorporate and reallege paragraphs 1-31 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-31.

33. United States Patent No. 6,211,244, entitled "Calcium Receptor-Active Compounds," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 3, 2001. A copy of the '244 patent is attached hereto as Exhibit A.

ANSWER: Barr admits that the '244 patent states on its face an issue date of April 3, 2001 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 33.

34. The '244 patent is assigned to NPS and NPS is the owner of the '244 patent.

ANSWER: On information and belief, Barr admits that the '244 patent is assigned to NPS.

35. Amgen has been and is the exclusive licensee of the '244 patent in the United States under a "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '244 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 35.

36. Amgen holds an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 36.

37. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 37.

38. The '244 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 38.

39. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr admits the allegations of paragraph 39.

40. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '244 patent.

ANSWER: Barr admits the allegations of paragraph 40.

41. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a certification and that the letter described why the asserted patents are invalid, unenforceable, and/or not infringed by Barr's ANDA products.

42. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr admits that an active ingredient in Barr's ANDA product for which it seeks approval is cinacalcet hydrochloride.

43. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '244 patent is invalid and/or not infringed.

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a Paragraph IV certification, and that the '224 patent is invalid and/or not infringed.

44. Barr has infringed at least one claim of the '244 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the `244 patent.

ANSWER: Barr denies the allegations of paragraph 44.

45. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '244 patent.

ANSWER: Barr denies the allegations of paragraph 45.

THIRD CLAIM FOR RELIEF

46. Plaintiffs incorporate and reallege paragraphs 1-45 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-45.

47. United States Patent No. 6,313,146 ("the 146 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on November 6, 2001. A copy of the '146 patent is attached hereto as Exhibit B.

ANSWER: Barr admits that the '146 patent states on its face an issue date of November 6, 2001 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 47.

48. The '146 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '146 patent.

ANSWER: On information and belief, Barr admits that the '146 patent is assigned to BWH and NPS.

49. Amgen has been and is the exclusive licensee of the '146 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '146 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 49.

50. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 50.

51. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 51.

52. The '146 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 52.

53. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 and therefore denies them.

54. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '146 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 and therefore denies them.

55. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 and therefore denies them.

56. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 and therefore denies them.

57. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '146 patent is invalid, not infringed and/or unenforceable.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 and therefore denies them.

58. Teva has infringed at least one claim of the '146 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the `146 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 and therefore denies them.

59. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '146 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 and therefore denies them.

60. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least

in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '146 patent under 35 U.S.C. § 271(e)(4).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 and therefore denies them.

FOURTH CLAIM FOR RELIEF

61. Plaintiffs incorporate and reallege paragraphs 1-60 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-60.

62. United States Patent No. 6,313,146 ("the '146 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on November 6, 2001. A copy of the '146 patent is attached hereto as Exhibit B.

ANSWER: Barr admits that the '146 patent states on its face an issue date of November 6, 2001 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 62.

63. The '146 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '146 patent.

ANSWER: On information and belief, Barr admits that the '146 patent is assigned to BWH and NPS.

64. Amgen has been and is the exclusive licensee of the '146 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '146 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 64.

65. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 65.

66. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 66.

67. The '146 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 67.

68. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr admits the allegations of paragraph 68.

69. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Ban's ANDA products") before the expiration of the '146 patent.

ANSWER: Barr admits the allegations of paragraph 69.

70. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a certification and that the letter described why the asserted patents are invalid, unenforceable, and/or not infringed by Barr's ANDA products.

71. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr admits that an active ingredient in Barr's ANDA product for which it seeks approval is cinacalcet hydrochloride.

72. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '146 patent is invalid and/or not infringed.

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a Paragraph IV certification, and that the '146 patent is invalid and/or not infringed.

73. Barr has infringed at least one claim of the '146 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the `146 patent.

ANSWER: Barr denies the allegations of paragraph 73.

74. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '146 patent.

ANSWER: Barr denies the allegations of paragraph 74.

FIFTH CLAIM FOR RELIEF

75. Plaintiffs incorporate and reallege paragraphs 1-74 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-74.

76. United States Patent No. 6,011,068 ("the '068 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on January 4, 2000. A copy of the '068 patent is attached hereto as Exhibit C.

ANSWER: Barr admits that the '068 patent states on its face an issue date of January 4, 2000 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 76.

77. The '068 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '068 patent.

ANSWER: On information and belief, Barr admits that the '068 patent is assigned to BWH and NPS.

78. Amgen has been and is the exclusive licensee of the '068 patent in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '068 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 78.

79. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 79.

80. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 80.

81. The '068 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 81.

82. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 82 and therefore denies them.

83. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '068 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 and therefore denies them.

84. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 84 and therefore denies them.

85. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 85 and therefore denies them.

86. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '068 patent is invalid, not infringed and/or unenforceable.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 and therefore denies them.

87. Teva has infringed at least one claim of the '068 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in

the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the `068 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 and therefore denies them.

88. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '068 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 and therefore denies them.

89. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '068 patent under 35 U.S.C. § 271(e)(4).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 89 and therefore denies them.

SIXTH CLAIM FOR RELIEF

90. Plaintiffs incorporate and reallege paragraphs 1-89 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-89.

91. United States Patent No. 6,011,068 ("the '068 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on January 4, 2000. A copy of the '068 patent is attached hereto as Exhibit C.

ANSWER: Barr admits that the '068 patent states on its face an issue date of January 4, 2000 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 91.

92. The ‘068 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the ‘068 patent.

ANSWER: On information and belief, Barr admits that the ‘068 patent is assigned to BWH and NPS.

93. Amgen has been and is the exclusive licensee of the ‘068 patent in the United States under the “Development and License Agreement” dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the ‘068 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 93.

94. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 94.

95. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 95.

96. The ‘068 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 96.

97. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr admits the allegations of paragraph 97.

98. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '068 patent.

ANSWER: Barr admits the allegations of paragraph 98.

99. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a certification and that the letter described why the asserted patents are invalid, unenforceable, and/or not infringed by Barr's ANDA products.

100. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr admits that an active ingredient in Barr's ANDA product for which it seeks approval is cinacalcet hydrochloride.

101. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '068 patent is invalid and/or not infringed.

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a Paragraph IV certification, and that the '068 patent is invalid and/or not infringed.

102. Barr has infringed at least one claim of the '068 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the `068 patent.

ANSWER: Barr denies the allegations of paragraph 102.

103. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '068 patent.

ANSWER: Barr denies the allegations of paragraph 103.

SEVENTH CLAIM FOR RELIEF

104. Plaintiffs incorporate and reallege paragraphs 1-103 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-103.

105. United States Patent No. 6,031,003 ("the '003 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on February 29, 2000. A copy of the '003 patent is attached hereto as Exhibit D.

ANSWER: Barr admits that the '003 patent states on its face an issue date of February 29, 2000 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 105.

106. The '003 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '003 patent.

ANSWER: On information and belief, Barr admits that the '003 patent is assigned to BWH and NPS.

107. Amgen has been and is the exclusive licensee of the '003 patent for certain compounds and in certain fields of use in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '003 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 107.

108. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 108.

109. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 109.

110. The '003 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 110.

111. Upon information and belief, Teva filed ANDA No. 90-539 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 111 and therefore denies them.

112. Upon information and belief, Teva's ANDA No. 90-539 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 90 mg base (hereinafter "Teva's ANDA products") before the expiration of the '003 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 112 and therefore denies them.

113. On or about June 12, 2008, BWH, NPS and Amgen received a letter from Teva dated June 11, 2008, purporting to be a Notice of Certification for ANDA No. 90-539 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 113 and therefore denies them.

114. Teva's letter alleges that the active ingredient in Teva's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 114 and therefore denies them.

115. Upon information and belief, Teva has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '003 patent is invalid, not infringed and/or unenforceable.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 115 and therefore denies them.

116. Teva has infringed at least one claim of the '003 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-539 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Teva's ANDA products before the expiration of the `003 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 and therefore denies them.

117. Upon information and belief, Teva's ANDA products would, if approved and marketed, infringe the '003 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 117 and therefore denies them.

118. Upon information and belief, Teva USA's actions relating to Teva USA's ANDA No. 90-539 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Teva Ltd. and therefore, Plaintiffs are entitled to full relief from Teva Ltd.'s acts of infringement of the '003 patent under 35 U.S.C. § 271(e)(4).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 118 and therefore denies them.

EIGHTH CLAIM FOR RELIEF

119. Plaintiffs incorporate and reallege paragraphs 1-118 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-118.

120. United States Patent No. 6,031,003 ("the '003 patent"), entitled "Calcium Receptor-Active Molecules," was duly and legally issued by the PTO on February 29, 2000. A copy of the '003 patent is attached hereto as Exhibit D.

ANSWER: Barr admits that the '003 patent states on its face an issue date of February 29, 2000 and is entitled "Calcium receptor-active compounds," but Barr denies the remaining allegations in paragraph 120.

121. The '003 patent is jointly assigned to BWH and NPS, and BWH and NPS are the owners of the '003 patent.

ANSWER: On information and belief, Barr admits that the '003 patent is assigned to BWH and NPS.

122. Amgen has been and is the exclusive licensee of the '003 patent for certain compounds and in certain fields of use in the United States under the "Development and License Agreement" dated March 18, 1996 between NPS and Amgen.

ANSWER: On information and belief, Barr admits that Amgen is the exclusive licensee of the '003 patent, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 122.

123. Amgen holds an approved New Drug Application No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004.

ANSWER: Barr admits the allegations of paragraph 123.

124. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

ANSWER: Barr admits the allegations of paragraph 124.

125. The '003 patent is listed in the Orange Book for NDA No. 21-688.

ANSWER: Barr admits the allegations of paragraph 125.

126. Upon information and belief, Barr filed ANDA No. 90-476 with the FDA under the provisions of 21 U.S.C. § 355(j).

ANSWER: Barr admits the allegations of paragraph 126.

127. Upon information and belief, Barr's ANDA No. 90-476 seeks FDA approval to engage in the commercial manufacture, use, and/or sale of generic cinacalcet hydrochloride tablets, EQ 30 mg base, EQ 60 mg base, EQ 90 mg base (hereinafter "Barr's ANDA products") before the expiration of the '003 patent.

ANSWER: Barr admits the allegations of paragraph 127.

128. On or about June 16, 2008, BWH, NPS and Amgen received a letter from Barr dated June 13, 2008, purporting to be a Notice of Certification for ANDA No. 90-476 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a certification and that the letter described why the asserted patents are invalid, unenforceable, and/or not infringed by Barr's ANDA products.

129. Barr's letter alleges that the active ingredient in Barr's ANDA products for which it seeks approval is cinacalcet hydrochloride.

ANSWER: Barr admits that an active ingredient in Barr's ANDA product for which it seeks approval is cinacalcet hydrochloride.

130. Upon information and belief, Barr has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '003 patent is invalid and/or not infringed.

ANSWER: Barr admits that in a letter dated June 13, 2008, it notified BWH, NPS and Amgen that Barr filed ANDA No. 90-476 and that Barr had filed a Paragraph IV certification, and that the '003 patent is invalid and/or not infringed.

131. Barr has infringed at least one claim of the '003 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-476 and seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of Barr's ANDA products before the expiration of the `003 patent.

ANSWER: Barr denies the allegations of paragraph 131.

132. Upon information and belief, Barr's ANDA products would, if approved and marketed, infringe the '003 patent.

ANSWER: Barr denies the allegations of paragraph 132.

NINTH CLAIM FOR RELIEF

133. Plaintiffs incorporate and reallege paragraphs 1-132 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-132.

134. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 134 and therefore denies them.

135. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 135 and therefore denies them.

136. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '244 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136 and therefore denies them.

137. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 137 and therefore denies them.

138. An actual controversy exists relating to Teva's threatened infringement of the '244 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 138 and therefore denies them.

TENTH CLAIM FOR RELIEF

139. Plaintiffs incorporate and reallege paragraphs 1-138 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-138.

140. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

ANSWER: The phrase "substantial preparations" is vague and undefined, and there is no stated "Tenth Claim" to which this allegation is shown to be relevant, so because it cannot be understood Barr therefore denies paragraph 140.

141. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr denies this allegation, because it does not have a present intention and may or may not commence sale of products immediately upon receiving approval from the FDA.

142. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '244 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr denies the allegations of paragraph 142.

143. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr denies the allegations of paragraph 143.

144. An actual controversy exists relating to Barr's threatened infringement of the '244 patent.

ANSWER: Barr denies the allegations of paragraph 144.

ELEVENTH CLAIM FOR RELIEF

145. Plaintiffs incorporate and reallege paragraphs 1-144 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-144.

146. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 146 and therefore denies them.

147. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 147 and therefore denies them.

148. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '146 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 148 and therefore denies them.

149. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 149 and therefore denies them.

150. An actual controversy exists relating to Teva's threatened infringement of the '146 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 150 and therefore denies them.

TWELFTH CLAIM FOR RELIEF

151. Plaintiffs incorporate and reallege paragraphs 1-150 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-150.

152. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

ANSWER: The phrase "substantial preparations" is vague and undefined, and there is no stated "Twelfth Claim" to which this allegation is shown to be relevant, so because it cannot be understood Barr therefore denies paragraph 152.

153. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr denies this allegation, because it does not have a present intention and may or may not commence sale of products immediately upon receiving approval from the FDA.

154. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '146 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr denies the allegations of paragraph 154.

155. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr denies the allegations of paragraph 155.

156. An actual controversy exists relating to Barr's threatened infringement of the '146 patent.

ANSWER: Barr denies the allegations of paragraph 156.

THIRTEENTH CLAIM FOR RELIEF

157. Plaintiffs incorporate and reallege paragraphs 1-156 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-156.

158. Upon information and belief, Teva has made substantial preparations to sell Teva's ANDA products.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 158 and therefore denies them.

159. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 159 and therefore denies them.

160. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '068 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 160 and therefore denies them.

161. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 161 and therefore denies them.

162. An actual controversy exists relating to Teva's threatened infringement of the '068 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 162 and therefore denies them.

FOURTEENTH CLAIM FOR RELIEF

163. Plaintiffs incorporate and reallege paragraphs 1-162 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-162.

164. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

ANSWER: The phrase "substantial preparations" is vague and undefined, and there is no stated "Fourteenth Claim" to which this allegation is shown to be relevant, so because it cannot be understood Barr therefore denies paragraph 164.

165. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr denies this allegation, because it does not have a present intention and may or may not commence sale of products immediately upon receiving approval from the FDA.

166. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '068 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr denies the allegations of paragraph 166.

167. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr denies the allegations of paragraph 167.

168. An actual controversy exists relating to Barr's threatened infringement of the '068 patent.

ANSWER: Barr denies the allegations of paragraph 168.

FIFTEENTH CLAIM FOR RELIEF

169. Plaintiffs incorporate and reallege paragraphs 1-168 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-168.

170. Upon information and belief; Teva has made substantial preparations to sell Teva's ANDA products.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 170 and therefore denies them.

171. Upon information and belief, Teva intends to commence sale of Teva's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 171 and therefore denies them.

172. The manufacture, importation, sale, and offer for sale of Teva's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172 and therefore denies them.

173. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 173 and therefore denies them.

174. An actual controversy exists relating to Teva's threatened infringement of the '003 patent.

ANSWER: Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 174 and therefore denies them.

SIXTEENTH CLAIM FOR RELIEF

175. Plaintiffs incorporate and reallege paragraphs 1-174 above, as if set forth specifically here.

ANSWER: Barr incorporates by reference its answers to paragraphs 1-174.

176. Upon information and belief, Barr has made substantial preparations to sell Barr's ANDA products.

ANSWER: The phrase "substantial preparations" is vague and undefined, and there is no stated "Sixteenth Claim" to which this allegation is shown to be relevant, so because it cannot be understood Barr therefore denies paragraph 176.

177. Upon information and belief, Barr intends to commence sale of Barr's ANDA products immediately upon receiving approval from the FDA.

ANSWER: Barr denies this allegation, because it does not have a present intention and may or may not commence sale of products immediately upon receiving approval from the FDA.

178. The manufacture, importation, sale, and offer for sale of Barr's ANDA products, once approved by the FDA, will directly infringe, induce an/or contribute to the infringement of one or more claims of the '003 patent under 35 U.S.C. § 271(a), (b) and (c).

ANSWER: Barr denies the allegations of paragraph 178.

179. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Barr denies the allegations of paragraph 179.

180. An actual controversy exists relating to Barr's threatened infringement of the '003 patent.

ANSWER: Barr denies the allegations of paragraph 180.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Barr does not actually infringe, and if marketed would not infringe, any valid claim of the asserted patents with its ANDA products that are the subject of ANDA No. 90-476.

Second Affirmative Defense

The claims of the asserted patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, 151, and/or 156 or other judicially-created bases for invalidity.

Third Affirmative Defense

The asserted patents are invalid due to apparently improper inventorship designations, by misjoinder and /or non-joinder.

Fourth Affirmative Defense

Plaintiffs are not entitled to relief because they have not demonstrated standing in order to bring the claims in this litigation.

Fifth Affirmative Defense

Plaintiffs are not entitled to relief because they are estopped by prosecution history and subject to prosecution history laches.

Sixth Affirmative Defense

Plaintiffs have not stated any claim for relief, and Claims for Relief 9 through 16 in particular should be dismissed.

WHEREFORE, Barr hereby demands judgment dismissing Plaintiffs' Complaint with prejudice, judgment for costs and fees of suit, and for such other relief as the Court may deem just.

COUNTERCLAIMS

For its counterclaims against The Brigham and Women's Hospital, Inc., NPS Pharmaceuticals, Inc., and Amgen Inc. (collectively "Plaintiffs" or "Counter-Defendants"), Defendant/Counter-Plaintiff Barr Laboratories, Inc. ("Barr") states as follows:

Parties

1. Barr Laboratories, Inc. is a Delaware corporation having its corporate offices and a principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, NY 10970.

2. On information and belief, The Brigham and Women's Hospital, Inc. ("BWH") is a hospital organized and existing under the laws of the State of Massachusetts, with its principal place of business at 75 Francis Street, Boston, Massachusetts 02115.

3. On information and belief, NPS Pharmaceuticals, Inc. ("NPS") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 550 Hills Drive, 3rd Floor, Bedminster, New Jersey 07921-1537.

4. On information and belief, Amgen, Inc. ("Amgen") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

Jurisdiction and Venue

5. This action arises under the patent laws of the United States of America. Subject matter jurisdiction is proper in this Court by Title 28, United States Code Sections 1331, 1338(a), 2201, and/or 2202.

6. Personal jurisdiction is proper in this Court because NPS and Amgen are Delaware corporations and because BWH, NPS and Amgen have subjected themselves to the jurisdiction of this Court by virtue of filing their Complaint.

7. Venue is proper in this Court under at least Title 28, United States Code Sections 1391 and 1400.

Background

8. On information and belief, the United States Patent and Trademark Office issued United States Patent No. 6,211,244 ("the '244 patent"), listing Edward F. Nemeth, Bradford C. Van Wagenen, Manuel F. Balandrin, Eric G. DelMar, and Scott T. Moe as inventors, and listing NPS as the assignee.

9. On information and belief, the United States Patent and Trademark Office issued United States Patent No. 6,313,146 ("the '146 patent"), listing Edward F. Nemeth, Bradford C. Van Wagenen, Manuel F. Balandrin, and Eric G. DelMar as inventors, and listing NPS as the assignee.

10. On information and belief, the United States Patent and Trademark Office issued United States Patent No. 6,011,068 ("the '068 patent"), listing Edward F. Nemeth, Bradford C.

Van Wagenen, Manuel F. Balandrin, Eric G. DelMar, and Scott T. Moe as inventors, and listing BWH and NPS as the assignees.

11. On information and belief, the United States Patent and Trademark Office issued United States Patent No. 6,031,003 ("the '003 patent"), listing Edward F. Nemeth, Bradford C. Van Wagenen, Manuel F. Balandrin, Eric G. DelMar, and Scott T. Moe as inventors, and listing BWH and NPS as the assignees.

12. Plaintiffs assert that Barr infringes and, if the products are marketed will infringe, claims of the '244, '146, '068, and '003 patents. Plaintiffs claim to own and have the right to enforce these asserted patents.

13. On information and belief, Amgen holds New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets, which the FDA approved on March 8, 2004.

14. On information and belief, NPS is the assignee of the '244 patent, Amgen is the exclusive licensee of the '244 patent, and BWH and NPS are the assignees of the '146, '068, and '003 patents.

15. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") authorize a generic drug company to submit an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA").

16. The FDCA requires NDA holders to disclose to the FDA the patent numbers and expiration dates of patents that the holders believe claim the "drug" for which the NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

17. The FDA then lists patents identified by the NDA holders in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly called the "Orange Book."

18. If a company seeks approval to market a generic version of an NDA drug before a patent listed in the Orange Book expires, then the company seeking to obtain approval must include in its ANDA submission a "certification" that the patent is invalid, unenforceable, and/or would not be infringed by the generic product. This type of certification is commonly called a "Paragraph IV Certification."

19. The ANDA applicant must send both the NDA holder and the patent holder a notice letter that includes a detailed statement of factual and legal bases for the ANDA applicant's opinion that the patent is invalid, unenforceable, and/or would not be infringed.

20. The FDA "Orange Book" lists the '244, '146, '068, and '003 patents associated with Amgen's NDA No. 21-688 for cinacalcet hydrochloride tablets.

21. Barr filed with the FDA an ANDA containing a Paragraph IV Certification to obtain approval to engage in the manufacture, use or sale of certain formulations and doses of cinacalcet hydrochloride ("Barr's ANDA products").

22. In a letter dated June 13, 2008, Barr's representative provided Plaintiffs with notice that it had submitted an ANDA with a Paragraph IV certification, and the notice letter contained a detailed factual and legal statement as to why the '244, '146, '068, and '003 patents are invalid, unenforceable and/or not infringed by Barr's ANDA products.

23. Plaintiffs filed the instant patent infringement lawsuit against Barr. In their complaint, Plaintiffs alleges that Barr's ANDA products will infringe the '244, '146, '068, and '003 patents, and Barr denies these allegations.

24. This case is an exceptional one, and Barr is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT I

Declaration of Non-Infringement of the ‘244, ‘146, ‘068, and ‘003 Patents

25. Barr re-alleges and incorporates herein the allegations of paragraphs 1-24.

26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the ‘244, ‘146, ‘068, and ‘003 patents will be infringed by the manufacture, use, offer for sale, or sale of Barr’s ANDA products.

27. Plaintiffs assert that the manufacture, use, offer for sale, or sale of Barr’s ANDA Products do and will infringe valid claims of the ‘244, ‘146, ‘068, and ‘003 patents.

28. The manufacture, use, offer for sale, or sale of Barr’s ANDA Products do not and will not infringe valid claims of the ‘244, ‘146, ‘068, and ‘003 patents.

29. A present, genuine justiciable controversy exists between Barr and Plaintiffs regarding the issue of whether the manufacture, use, offer for sale, or sale of Barr’s ANDA products would infringe claims of the ‘244, ‘146, ‘068, and ‘003 patents.

30. Barr is entitled to a declaration that the manufacture, use, offer for sale, or sale of its ANDA products do not and will not infringe claims of the ‘244, ‘146, ‘068, and ‘003 patents.

COUNT II
Declaration of Invalidity of the '244, '146, '068, and '003 Patents

31. Barr re-alleges and incorporates herein the allegations of paragraphs 1-30.

32. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '244, '146, '068, and '003 patents are invalid.

33. Plaintiffs assert that valid claims of the '244, '146, '068, and '003 patents are infringed.

34. The manufacture, use, offer for sale, or sale of Barr's ANDA Products do not and will not infringe valid claims of the '244, '146, '068, and '003 patents, as the claims of those patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, 151, 156, or other judicially-created bases for invalidation.

35. The claims of asserted patents '244, '146, '068, and '003 are also invalid for inventor misjoinder or non-joinder, as on information and belief the incorrect inventors were named and/or not all inventors were named.

36. A present, genuine, and justiciable controversy exists between Barr and Plaintiffs regarding the validity of the '244, '146, '068, and '003 patents.

37. Barr is entitled to a declaration that claims of the '244, '146, '068, and '003 patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Barr Laboratories, Inc. prays that the Court enter judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

1. For a declaration that Barr Laboratories, Inc.'s ANDA Products do not and will not infringe valid claims of U.S. Patent Nos. 6,211,244 ("the '244 patent"); 6,313,146 ("the '146 patent"); 6,011,068 ("the '068 patent"); and 6,031,003 ("the '003 patent");

2. For a declaration that the claims of U.S. Patent Nos. 6,211,244 ("the '244 patent"); 6,313,146 ("the '146 patent"); 6,011,068 ("the '068 patent"); and 6,031,003 ("the '003 patent") are invalid;

3. For an award of attorneys' fees pursuant to 35 U.S.C. § 285;

4. For an award of costs; and

5. For such other relief as the Court determines to be just and proper.

JURY DEMAND

Defendant/Counterclaim-Plaintiff Barr Laboratories, Inc. requests a jury trial on all issues so triable.

Dated: August 18, 2008

/s/ Richard K. Herrmann

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